REMARKS

Claims 1 to 33 are pending. Following a restriction requirement, elected claims 1-6, 14, 17, and 32-33 (compositions related to *pagA* sequences) have been examined and stand rejected. The Office action fails to state that the restriction requirement has been made final, but the Examiner's comments in response to Applicants' traversal and the examination of only the elected claims are consistent with a final restriction requirement. If this is incorrect, the Examiner is requested to clarify.

Applicants note that the Office action at page 3 and in form PTOL-326, line 4a, state that claims 7-13, 15, 16, 18 **and** 31 are withdrawn from consideration (emphasis added). Applicants presume that a typographical error occurred and that the Office action intended to say that claims 7-13, 15, 16, 18 **to** 31 are withdrawn from consideration. Based on this presumption, Applicants have provisionally listed claims 18 to 31 as "Withdrawn" in the "CLAIMS" section of this response. Applicants respectfully request clarification in the next Office action regarding the status of claims 19 to 30.

In this amendment, claims 1-6, 14, 17, 20, 22, 23, 32 and 33 have been amended. Withdrawn claims 20, 22 and 23 have been amended consistent with amended claim 1 and are presented for consideration consistent with the rejoinder of process claims as a matter of right if patentable subject matter is found in the composition claim.

Rejections under 35 U.S.C. § 101

Claims 1-6 and 14 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter because allegedly the claimed oligonucleotides have the same characteristics as found in nature. No art has been cited to support the statement that the "oligonucleotide as claimed, has the same characteristics as that found in nature." To avoid possible "procedural default" (*See In re Sun*, 31 U.S.P.Q.2d 1451, 1455 (Fed. Cir. 1993, unpublished)), and to avoid having this assertion "establish[ed] ... as admitted prior art" Applicants request that the Examiner either provide a reference (see 37 C.F.R. §1.104(c)(2) and M.P.E.P. § 706.02(a)) or an affidavit under 37 C.F.R. § 1.104(d)(2) in support of this assertion.

Claims 1-6 and 14 have been amended to clarify that the claimed compositions include "synthetic" oligonucleotides, consistent with the disclosure (e.g., page 12, lines 15-18). Applicants respectfully request withdrawal of the rejections based on 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-6, 14, 17, 32 and 33 stand rejected under 35 U.S.C. § 112, second paragraph.

Claim 1 has been amended to recite "A composition comprising a synthetic oligonucleotide..." and claims 2-6 have been amended to refer to "The composition of claim 1, wherein the synthetic oligonucleotide ...." Amended claim 1 also deleted SEQ ID numbers for non-elected sequences, i.e., not *pagA* sequences.

Claims 1-6 were rejected because the Examiner stated that the claims included "recitation of 'contains' and 'consists of' in the same claim and is not clear what are the metes and bound of these terms." Applicants respectfully disagree with this rejection for the following reasons. Claim 1 does not recite "contains" but instead recites "a sequence **contained in** a *B. anthracis* target sequence". The plain meaning of the word "contains" is different from the plain meaning of the phrase "contained in". For example, a jar that *contains* candy is different from the candy *contained in* the jar. Claim 1 also recites that the target sequence is one "consisting of" specified SEQ ID numbers (or their complementary or RNA equivalent sequences). Read as a whole, the claimed compositions include one or more synthetic oligonucleotides in a recited size range (about 20 to 40 nucleotides) where an oligonucleotide has the property that it hybridizes specifically to a sequence contained in a defined target sequence (consisting of the specified SEQ ID numbers, their complementary or RNA equivalent sequences). Therefore, Applicants submit that the metes and bounds of claims 1-6 are properly presented and request withdrawal of the rejections of claims 1-6.

Dependent claims 2-6, 14 and 17 were rejected for using the terms "an oligonucleotide" instead of "the oligonucleotide" referring to the antecedent term in claim 1. Applicants have amended claims 2-6, 14, and 17 to refer to the proper antecedent terms of claim 1 ("The composition of claim 1, wherein the

synthetic oligonucleotide ...”). These rejections are moot in view of the amendments.

Dependent claim 3-6 stand rejected for allegedly being unclear “which oligonucleotide consist SEQ.ID.NO: 1 or 2 or 3 etc since more than one oligonucleotide is recited in the claims.” Applicants respectfully disagree with this rejection for the following reasons. Each of amended claims 3-6 recites a composition according to claim 1, wherein an oligonucleotide that hybridizes specifically to the *pagA* target sequence contained in a particular sequence (by SEQ ID number) consists of one embodiment specified by a SEQ ID number or another embodiment specified by another SEQ ID number. Applicants are unaware of any law or rule that prohibits presentation of more than one embodiment in a claim and, accordingly, request clarification from the Examiner on this rejection. In the absence of such a prohibition, Applicants respectfully submit that claims 3-6 comply with the requirements of 35 U.S.C. § 112, second paragraph and request withdrawal of the rejections.

Claims 32 and 33 were rejected as unclear as to what was being claimed because both claims recited two target sequences (*pagA* and *capB*). Claim 32 was objected to as depending from a non-elected method claim. Claim 32 has been amended to be an independent composition claim. Claims 32 and 33 have been amended consistent with the election of *pagA* related embodiments of the disclosed invention and consistent with language of claim 1. Therefore, Applicants respectfully submit that amended claims 32 and 33 are in condition for allowance.

Based on the arguments presented above, Applicants respectfully submit that claims 1-6, 14, 17, 32 and 33 comply with the requirements of 35 U.S.C. § 112, and request allowance of these claims.

Rejections under 35 U.S.C. § 102(e)

Claims 1-6 and 14 have been rejected under § 102(e) as allegedly anticipated by Lee et al., US Patent No. 6,770,479, because the Examiner stated that “Lee et al. disclose an isolated nucleotide sequence SEQ ID NO:4 ... [of] *B. anthracis* which is 100% identical to the claimed SEQ ID NO: 21, 22, 23, and 24 and therefore they hybridize to the claimed oligonucleotide.”

To be anticipated, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Fndn. v. Genentec, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001, 1010, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).

Applicants respectfully disagree with this rejection for the following reasons. As described above under the section related to rejections of claims 1-6 under 35 U.S.C. § 112, second paragraph, the claimed compositions are oligonucleotides in a specified size range that hybridize specifically to a specified target sequence (consisting of specified SEQ ID numbers, their complementary or RNA equivalent sequences). Preferred embodiments of such compositions are defined by dependent claims 3-6 which include sequences of additional specified SEQ ID numbers.

The sequence disclosed by Lee et al. (SEQ ID NO:4 in US Patent No. 6,770,479) is a 1,710 nucleotide sequence which contains a subsequence identical to at least one of Applicants' target sequences (a 57 nucleotide sequence). That is, the prior art discloses a 1,710 nucleotide sequence that contains a smaller target sequence identified by Applicants. The 1,710 nucleotide sequence of the prior art, however, does not fall in the size range of the claimed oligonucleotides. Thus, a person of ordinary skill in the field of molecular biology would not consider the disclosure of the 1,710 nucleotide sequence of Lee et al. to be identical to the claimed invention. Because of this difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention, the cited prior art does not anticipate the claimed invention. Therefore, Applicants respectfully request withdrawal of the rejections of claims 1-6 and 14 under § 102(e).

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims, as amended, are patentable and in condition for allowance. Accordingly, withdrawal of the rejections and allowance of the application is earnestly solicited. The undersigned has made a good-faith effort to address all the points raised in this Office Action and to place the claims in condition for allowance. However if minor matters remain that could be resolved by telephone interview, the Examiner is invited to contact the undersigned at the number below.

Authorization is hereby provided to debit any fees associated with filing of this amendment, including the fee for a one-month extension of time, to the US Patent and Trademark deposit account number 07-0835 maintained in the name of Gen-Probe Incorporated.

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being filed electronically, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Respectfully submitted,

Date: October 6, 2006

By: /Christine A. Gritzmacher/
Christine A. Gritzmacher
Reg. No. 40,627

GEN-PROBE INCORPORATED
Patent Department
10210 Genetic Center Drive
San Diego, California 92121
Tel.: (858) 410-8926
FAX: (858) 410-8928